PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference E049924-MAM	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IT 03/00374	International filing date *(day/month/year)* 16.06.2003	Priority date *(day/month/year)* 16.06.2003
International Patent Classification (IPC) or both national classification and IPC A61M25/10		
Applicant ARTECH S.R.L. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05.01.2005	06.10.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Rosenblatt, T Telephone No. +49 89 2399-8732

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT 03/00374

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1, 3-18	as originally filed
2	received on 02.08.2005 with letter of 27.07.2005

Claims, Numbers

1-22	filed with telefax on 22.09.2005

Drawings, Sheets

1/8-8/8	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 21,22

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 21,22

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-20
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
   D1: US-A-5908407,
   D2: US-A-6558401,
   D3: US-A-6017323,
   D4: US-A-5454788.

2.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows in figure 4 a catheter for medical applications, suitable for being inserted into a duct comprising first and second vessels the, comprising the following features (the references in parentheses applying to this document):

a catheter body (90) which extends from a proximal end (30) to a distal end (32), said catheter body comprising a main cavity (101), bounded by a lateral wall (implicit, see figures 5, 6), which passes through the catheter body between the proximal end and the distal end, suitable for receiving a guide cable for the insertion of the catheter into the first vessel and at least one opening (114,116,118) disposed on the lateral wall at the distal end and suitable for perfusing a substance, whereby the catheter body, at a portion of the lateral wall comprised between said at least one opening and said distal end comprises first and second occluding means (41,127), wherein the first occluding means (41) are suitable for at least partially occluding a gap between the catheter body and an inner wall of the first vessel, and the second occluding means (127, see fig. 7) can be associated internally with said main cavity and are suitable for at least partially occluding said main cavity, said first and second occluding means defining a direction of outflow of a fluid from the main cavity of the catheter body to the second vessel through said at least one opening of the catheter body.

2.2 The subject-matter of claim 1 differs from this known catheter in that all openings pass through the lateral wall and are in fluid communication with the main cavity, the openings being not aligned, and that the area of "the at least one opening" is not less than the area of the cavity of the distal end of the catheter.

It follows that the subject-matter of claim 1 is new (Art. 33(2) PCT).

2.3 It is noted nevertheless, that the subject-matter lacks clarity (Art. 6 PCT), since the preamble of the claim defines the feature "at least one opening", so covering also the possibility of having a single opening. In such a case the feature "not aligned" does not make any sense. Since the description does not disclose any embodiment with a single opening, the claim should have been correctly formulated by defining in the preamble a "plurality of openings".

Also an inconsistency arises with respect to the description in view of the feature "area of the opening not less than the area of the (main) cavity". On page 5, lines 22 to 25 reference is made to the "sum of the areas", which is different from the present definition in claim 1.

Moreover, the comparison between the area of the lateral openings with the area of the main cavity does not appear to make any technical sense. The applicant indicated in his fax of 22.9.05, that the fluid would experience a greater resistance in exiting from the distal end compared to the lateral openings. But this is correct only under the condition that a distal opening would be present. The claim however does not define such an opening.

In view of the description (e.g. page 7, lines 1-3, figures), the claim's subject-matter is nevertheless understood, for the purpose of considering the inventive activity, as if such an opening is present.

2.4 The technical effect is a more uniform outflow of fluid in the area between the two occluding balloons, where also more fluid passes through these lateral opening than through a main aperture (see 2.3).

2.5 The combination of the distinguishing features defined is not rendered obvious through the available prior art, so that the subject-matter of claim 1 is considered to involve an inventive activity (Art. 33(3) PCT).

3. Claims 2-19 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

4. The catheter according to claims 1 to 20 may be industrially manufactured and commercialised, so that the requirement of Art. 33(4) PCT is also met.

Such techniques, defined as direct selective infusion, consist in directly selecting the vessel to be infused, by means of a catheter. They therefore involve the need to span with the catheter a main vessel from which branches off the vessel to be infused, and to enter the bifurcation with the catheter in order to be able to inject the substance directly into the preselected vessel.

These known catheters have extremely soft and flexible ends which have the task of adapting to the curvatures of the vessels to enter them.

Sometimes these catheters have the drawback of dissecting the vessels, in particular vessels of reduced calibre or having accentuated curvatures at the branchings from which they start. The lesions caused by incorrect insertion of a catheter may be extremely serious, so that such a known technique is not used for vessels having the above-mentioned characteristics.

It is known from US 5908407 and US 6558401 B1, to provide catheters comprising occluding means both upstream and downstream an aperture to deliver a fluid in a selected vein. These known catheters are not able to perfuse small quantities of a liquid directly in a target vein.

The problem underlying the present invention is that of providing a catheter which solves the drawbacks cited with reference to the prior art.

Such drawbacks and limitations are solved effectively by a catheter according to claim 1.

Other embodiments of the catheter according to the invention are described in the subsequent claims.

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C L A I M S

1. A catheter (4) for medical applications, suitable for being inserted into a duct (5) comprising a first vessel (6) and a second vessel (7) which branches off from said first vessel (6), the catheter (4) comprising a catheter body (10) which extends from a proximal end (12) to a distal end (16), said catheter body (10) comprising a main cavity (20), bounded by a lateral wall (28), which passes through the catheter body (10) between the proximal end (12) and the distal end (16), suitable for receiving a guide cable for the insertion of the catheter (4) into the first vessel (6), and at least one opening (24), disposed on the lateral wall (28) at the distal end (16) and suitable for perfusing a substance, characterized in that the catheter body (10), at a portion of the lateral wall (28) comprised between said at least one opening (24) and said distal end (16), comprises

first and second occluding means (60, 62), wherein the first occluding means (60) are suitable for at least partially occluding a gap (63) between the catheter body (10) and an inner wall (32) of the first vessel (6), and the second occluding means (62) can be associated internally with said main cavity (20) and are suitable for at least partially occluding said main cavity (20),

said first and second occluding means (60, 62) defining a preferred direction of outflow of a fluid from the main cavity (20) of the catheter body (10) to the second vessel (7), through said at least one opening (24) of the catheter body (10);

wherein

all the openings (24) pass through said lateral wall (28) and are in fluid communication with the main cavity (20)

said at least one opening (24) is such that the area of the at least one opening (24) is not less than the area of the cavity of the distal end (16) of the catheter body (10)

said openings (24) are not aligned with one another with respect to a main axis of extension (X) of the catheter body (10).

2. A catheter according to claim 1, wherein said openings (24) are disposed substantially in a helical direction with respect to the main axis of extension (X) of the catheter body (10).

3. A catheter according to claim 1 or 2, wherein said first and second occluding means (60, 62) co-operate with each other to create a resistance to the passage of fluid through said distal end (16), favouring an outflow of fluid through said at least one opening (24).

4. A catheter according to claim 1, 2 or 3, wherein

said first and second occluding means (60, 62), at a portion of the catheter body (10) comprised between said at least one opening (24) and said distal end (16), substantially effect the occlusion of the first vessel (6) into which the catheter (4) is inserted, so as to direct a flow of fluid into the second vessel (7), through said at least one opening (24).

5. A catheter according to any one of the preceding claims, wherein said first occluding means (60) comprise an inflatable element (64) positioned round the catheter body (10), said inflatable element (64), in a rest state, adhering substantially to the catheter body (10), and in a working state being substantially in contact with an inner wall (32) of said first vessel (6).

6. A catheter according to claim 5, wherein said inflatable element (64) is in fluid connection with the proximal end (12) so as to be operable from said proximal end (12).

7. A catheter according to any one of the preceding claims, wherein said catheter body (10) comprises a secondary cavity (36), which extends from the proximal end (12) to the distal end (16) and is hermetically separated from said main cavity (20), said secondary cavity (36) being in fluid connection with said first occluding means

(60) so as to permit the actuation of said first occluding means (60).

8. A catheter according to claim 7, wherein said secondary cavity (36) is produced in a thickness of said lateral wall (28) of said catheter body (10).

9. A catheter according to claim 7 or 8, wherein the catheter body (10) has an oval cross-section having a first pole (37') more pronounced than a second pole (37") diametrically opposed to the first pole (37'), so that the lateral wall (28), at the first pole (37'), receives said secondary cavity (36).

10. A catheter according to any one of the preceding claims, wherein said second occluding means (62) comprise an occluding body (68), suitable for being introduced into said main cavity (20), and an insertion cable (72) firmly connected to said occluding body (68) so as to allow the insertion of the occluding body (68) through the main cavity (20).

11. A catheter according to claim 10, wherein said occluding body (68) is substantially spherical in shape.

12. A catheter according to claim 10, wherein said occluding body (68) is substantially frustoconical in shape.

13. A catheter according to any one of the preceding

claims, wherein said catheter body (10), at said distal end (16), comprises a portion with tapered profile (46) so as to reduce the cavity of the catheter body (10) at the distal end (16).

14. A catheter according to any one of the preceding claims, wherein said second occluding means (62), at said distal end (16), comprise a membrane (76) suitable for at least partially occluding said main cavity (20) and having a hole (80) suitable for allowing the passage of the guide cable of said catheter (4).

15. A catheter according to claim 14, wherein said membrane (76) is firmly connected to the distal end (16) of the catheter body (10).

16. A catheter according to any one of the preceding claims, wherein said second occluding means (62) are made of a material suitable for being sterilized.

17. A catheter according to any one of the preceding claims, comprising, at said proximal end (12), a main pathway (96), suitable for receiving said second occluding means (62) and fluidly connected to said main cavity (20).

18. A catheter according to claim 17, wherein said main pathway (96) comprises a threaded section (100) capable of producing a threaded connection with a

corresponding threaded portion of said second occluding means (62).

19. A catheter according to any one of the preceding claims, wherein said proximal end (12) comprises a secondary pathway (108), fluidly connected to said secondary cavity (36), and suitable for receiving at the inlet a fluid for allowing the actuation of said first occluding means (60).

20. A catheter according to any one of the preceding claims, wherein said proximal end (12) comprises an infusion pathway (112), fluidly connected to said main cavity (20) and suitable for receiving at the inlet a fluid, so as to allow the flow of the fluid from the proximal end (12) to the distal end (16).

21. A method for the use of a catheter according to any one of the preceding claims, said catheter (4) comprising first and second occluding means (60, 62) said method comprising the steps of:

- inserting the catheter (4) into a first vessel (6), by means of a guide cable, so that the distal end (16) of the catheter (4) passes beyond the branching (8) from which starts the second vessel (7) into which it is intended to perfuse a substance;
- withdrawing the guide cable and inserting the second

occluding means (62);

- actuating the first occluding means (60) so as to occlude at least partially the gap (63) between the catheter body (10) and the inner wall (32) of the first vessel (6);

- injecting the substance into the main cavity (20) of the catheter (4) so as to direct the substance from the at least one opening (24) of the lateral wall (28) of the catheter body (10) to the bifurcation (8) from which the second vessel (7) starts.

22. The method of claim 21, wherein the first vessel is a subclavian artery and the second vessel is a mammary artery.